



Anticipating a Yes: an Early Analysis of the **NOMINATE** Study

DETERMINING DIFFERENCES BETWEEN
PARTICIPANTS WHO CONSENT VERSUS
THOSE THAT DO NOT IN AN ONGOING
CLINICAL COHORT STUDY

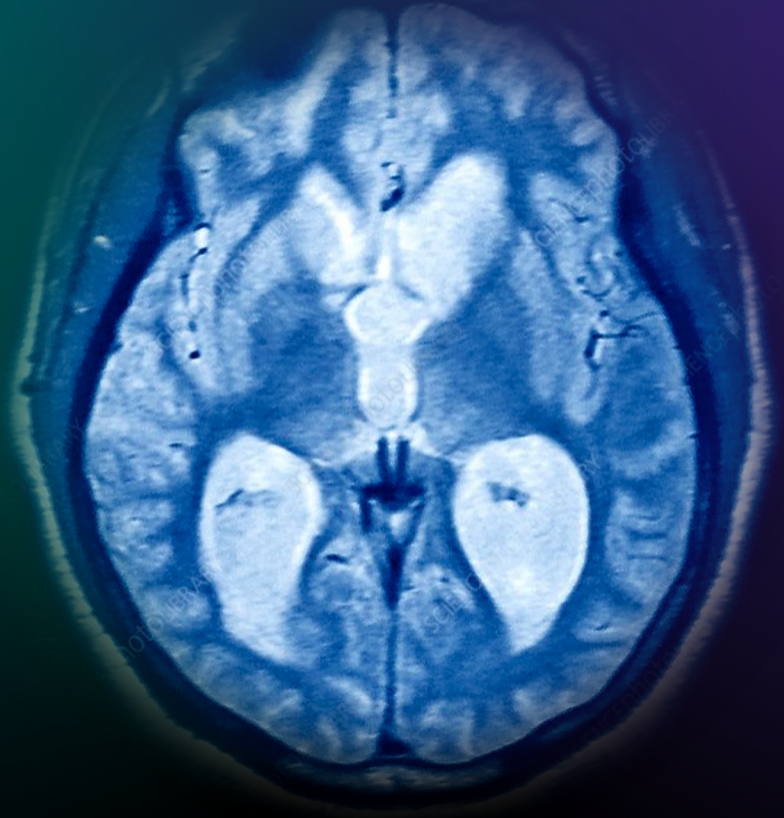
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Graduating Junior in Neuroscience
DREAMS Spring 2023

NOMINATE

- **determiNants Of AlzheiMer's Disease iN Atrial fibrillation aparT from stroke**
- Overarching goal:
 - To determine the differences between:
 - Mean levels of plasma biomarkers that suggest Alzheimer's disease
 - Cerebral magnetic resonance imaging (MRI) findings that suggest dementia
 - Among patients with 1) high-risk cardiovascular disease (CVD) and NO atrial fibrillation (AF) versus 2) high-risk cardiovascular disease (CVD) AND atrial fibrillation (AF)
- Why?
 - AF can cause stroke
 - Stroke can cause dementia
 - But does AF apart from stroke cause dementia?

Michelle C. Johansen MD PhD,
Principal Investigator
Associate Professor of
Neurology @ JHMI





Atrial Fibrillation and Cognitive Impairment

- FROM THE BLOOD DRAW:
 - Look for levels of AD-associated biomarkers
 - P-tau181
 - A β 42/A β 40
 - Neurofilament Light Chain (NFL)



- FROM THE MRI
 - Determine brain volumes that lie in important cognition areas
 - Look for markers of silent cerebrovascular disease
 - Infarction
 - White matter disease

My role in the study



1st
undergrad in
the lab!

Determining Eligibility from the medical record

- Must have at least 2 out of 6 pre-specified CVD risk factors
- Must not have prior cognitive impairment
- Must not have had a stroke
- Must be 55 years of age or older
- Cannot have had heart failure
- Can provide consent
- Able to get a blood draw

Approaching and consenting the patient

- Study setting is the Johns Hopkins outpatient Cardiology Unit
- Approaching participants having never met them previously
- Administering a cognitive screener
- Providing informed consent and asking questions
- If a yes, escorting to the phlebotomy lab for study blood draw, then transfer of sample to the cell lab for analysis

Cardiovascular Risk Factors

- **Part of the eligibility criteria is to have at least 2 out of the 7 following risk factors:**

Prevalent
Cardiovascular
Disease

Family History of
Cardiovascular
Disease

Hypertension

Hyperlipidemia

Obesity

Diabetes

Current
Tobacco Abuse

My Study Question

- **Of the patients who were approached for the study, what were the characteristics of those who consented for the study versus those who did not?**
- Age?
- Sex?
- Race?
- Prior medical history?

A Breakdown of Eligible Patients

Consented?	Patients	% Total
No	189	73
Yes	35	13
Not approached	36	14
Total	260	100

- **260 eligible patients** from August 2022 to March 2023
- **224 patients** approached for consent
 - why not all 260?
- **35 patients** consented for blood draw

Eligible Patient Demographics

- **Race**

- 58 (22%) Black
- 175 (67%) White
- 27 (11%) Other

- **Sex**

- 143 (55%) Male
- 117 (45%) Female

- **Age**

- Mean Age: 70
- IQR:

- **Cardiovascular Risk Factors**

- All eligible patients must have at least 2 risk factors
- Mean number of RFs: 3.25

Eligible Patient Summary Characteristics by Consent Status

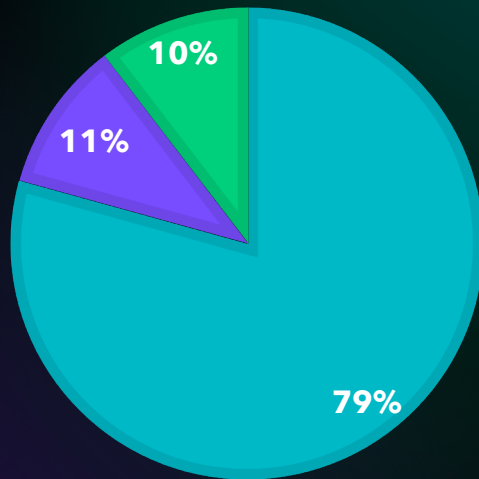
- No individual characteristic explained why a participant who consent or not among those that were analyzed.
- **While not significant, it may be that having a Family History of CVD and being over the age of 70 years old are important considerations in the consenting process.**

	Declined Consent	Provided Consent	Relevant P-values
Total Number	189	35	
Female	86	16	0.98
Male	103	19	
Mean Sum of Risk Factors	3.23	3.11	0.57
Prevalent CVD	118	23	0.71
Family History of CVD	80	20	0.067
Hypertension	145	27	0.96
Hyperlipidemia	135	23	0.50
Obesity	68	8	0.13
Diabetes	56	7	0.24
Current Tobacco Abuse (Y/N)	9	1	0.62
Prevalent AF	38	7	0.99
Mean Age	71.2	70.8	0.29
Over the Age of 70	94	23	0.082

Percentage who consented among eligible participants by race

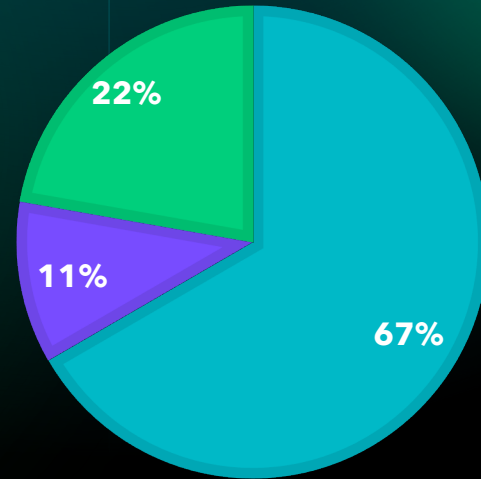
ELIGIBLE BLACK

■ No ■ Yes ■ Not Approached



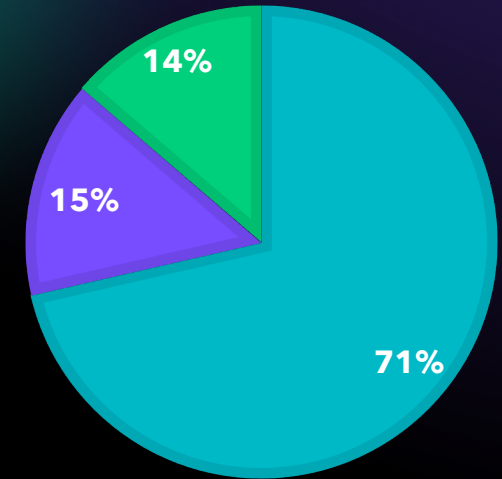
ELIGIBLE OTHER

■ No ■ Yes ■ Not Approached



ELIGIBLE WHITE

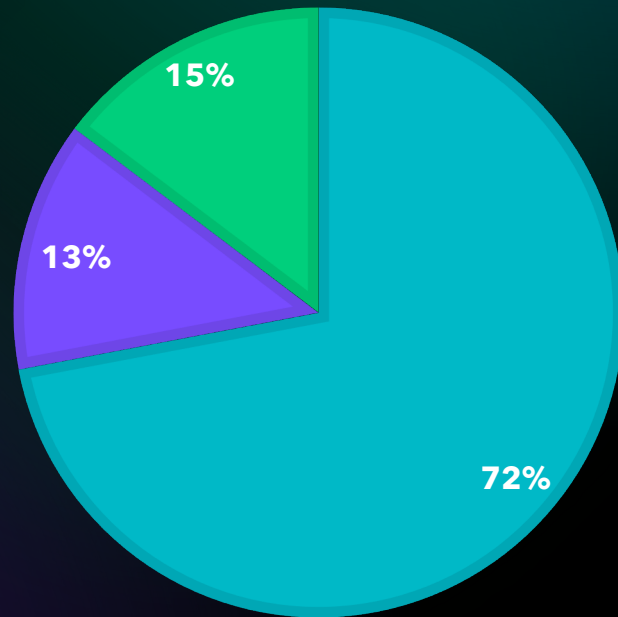
■ No ■ Yes ■ Not Approached



Percentage who consented among eligible participants by sex

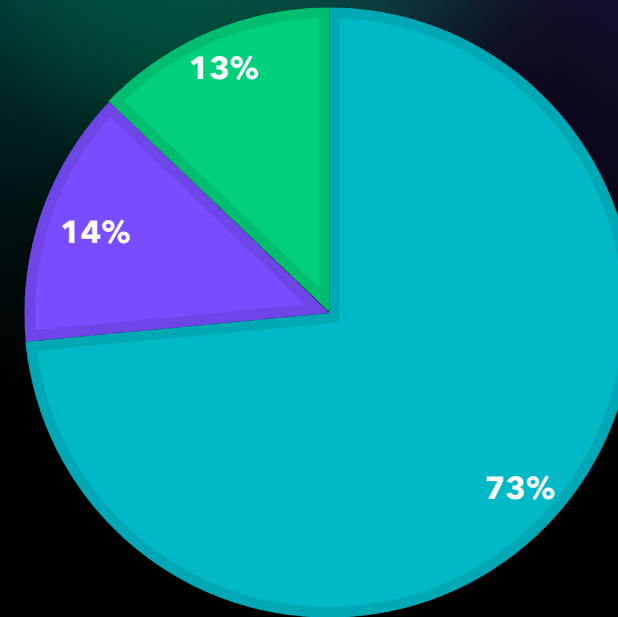
ELIGIBLE MALES

■ No ■ Yes ■ Not Approached



ELIGIBLE FEMALES

■ No ■ Yes ■ Not Approached

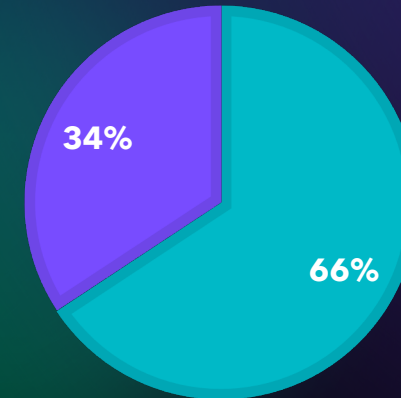


By Age...

- All approached patients 55 years or older
- Mean age of approached patients: 70
- While this data is not significant, there is a **trend in the consented patient population towards patients older than 70 years of age**
- P-value of 0.082 between consented individuals and those who declined
- Could become MORE significant with more people enrolled in the study

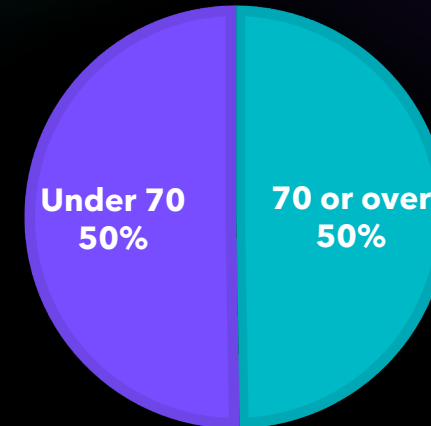
PATIENTS WHO CONSENTED

■ 70 or over ■ Under 70



PATIENTS WHO DECLINED

■ 70 or over ■ Under 70



By Risk Factors for Cardiovascular Disease

Of the 260 eligible patients...

- 165 had prevalent CVD
- 115 had family history of CVD
- 203 had hypertension
- 179 had hyperlipidemia
- 93 had obesity
- 77 had diabetes
- 15 had current tobacco abuse

Of those who were approached...

	Declined Consent	Provided Consent	Relevant P-value
Prevalent CVD	118	23	0.71
Family History of CVD	80	20	0.067
Hypertension	145	27	0.96
Hyperlipidemia	135	23	0.50
Obesity	68	8	0.13
Diabetes	56	7	0.24
Current Tobacco Abuse (Y/N)	9	1	0.62

Family History of Cardiovascular Disease

- While not significant, P-value of 0.067 indicates that the population of those who consented for the study seems to **favor those who have a family history of CVD**
- Potential causes
 - Know someone with AF or CVD, want to know more!
 - From personal experience...
 - Patients reference family members that could be helped by this research
 - Have some sort of vested interest



MRI Subsection - Data Overview

254 patients eligible for MRI

220 approached for consent

24 patients agreed to participate

This is optional!

Eligible Patient Summary for MRI

- Same statistics done as blood draw
- No significant differences
- Mean sum of risk factors and diabetes approaching significance
- More patients needed?

	Declined Consent	Provided Consent	Relevant P-values
Total Number	196	24	
Female	92	12	0.98
Male	104	12	
Mean Sum of Risk Factors	3.3	2.8	0.049
Prevalent CVD	127	12	0.16
Family History of CVD	93	8	0.50
Hypertension	151	19	0.81
Hyperlipidemia	136	14	0.27
Obesity	64	11	0.20
Diabetes	58	3	0.077
Current Tobacco Abuse (Y/N)	14	0	0.18
Mean Age	71	74	0.17
Over the Age of 70	96	15	0.21



From what we evaluated, we did not detect a difference in characteristics among those who provided consent and those who did not

THE DECISION TO PROVIDE INFORMED CONSENT IS LIKELY MORE NUANCED

What does this tell us about our study?

From what we evaluated, no differences in population

Something else involved?
Socioeconomic status? Prior research participation?

Can reference when validating final conclusions from research

Future of NOMINATE

- 2 years of data collection
- 150 patients
- Continue this way, collecting data responsibly



Mya Watson



Samantha Lee



Emma Gootee

My study team members, special thanks to Emma Gootee for helping with data analysis!